



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,469	11/01/1999	DAVID M. ARMISTEAD	VPI/95-09-DI	8756

7590

03/20/2003

JAMES F HALEY JR
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 100201104

EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/20/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/431,469

Applicant(s)

ARMISTEAD ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 23,24.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

In view of the new rejections set forth below, the finality of the office action sent 7/17/02 is hereby withdrawn. Further, the indication of allowability of claims 25-30 is also withdrawn in view of the rejections set forth below. The examiner regrets any confusion and urges applicants to review the Trilateral Project WM4 Report on Comparative Study on Protein 3-Dimensional (3-D) Structure Related Claims at: http://www.uspto.gov/web/tws/wm4/wm4_3d/report.htm for a complete analysis of patentability issues with regard to claims reciting crystallographic coordinates. The examiner considers point A4 in the US notes regarding Cases 6 and 7 to be especially relevant.

Any rejections and objections not set forth below are hereby withdrawn. The amendment filed 10/17/02 has been entered. A nonfinal office action on the merits of pending claims 19-30 follows.

Drawings

The drawings have been approved by the draftsman.

35 USC § 101/112

The claims are directed to methods of identifying compounds which bind to calcineurin; i.e. *in silico* screening methods that have a practical application, and are therefore statutory under 35 USC 101. The specification discloses on pages 2-3 that compounds which bind to a phosphatase binding site and/or an FK506/FKB12 binding site may inhibit the phosphatase activity of calcineurin. The specification further discloses, on pages 1 and 3, a correlation between inhibitors of calcineurin and the utility of such compounds as immunosuppressants. As the utility of the method is based

on the utility of the compounds identified, and the specification sets forth a credible utility for such compounds, the claims have utility under 35 USC 112.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over HENDRY et al. (US 5,705,335).

HENDRY teaches a method to evaluate the ability of a chemical compound to associate with another (the "degree of fit" of binding to a pharmacophore) wherein a ligand is docked (fitting operation) into a binding site, and the results evaluated (col. 7,

Art Unit: 1631

lines 9-24). HENDRY also teaches "outputting" results of his fitting method (Figures 1-4). HENDRY further teaches that compounds identified using a computer modeling/docking algorithm may be synthesized (col. 10, lines 17-21) and evaluated for binding in *in vitro* assays (col. 10, line 40-col. 11, line 64), thereby making obvious all of the steps of the claimed methods. It is noted that the structure coordinates recited in the claims are nonfunctional descriptive material as they do not impose a change on the processing steps used in the claimed methods. Algorithms to fit or dock a molecular entity into a binding site of a molecule or molecular complex are known in the art, as set forth above. A method of using a known algorithm for its known purpose does not become nonobvious merely because new data is available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106. Applicant is also directed to the Trilateral Project WM4 Report on Comparative Study on Protein 3-Dimensional (3-D) Structure Related Claims at: http://www.uspto.gov/web/tws/wm4/wm4_3d/report.htm

Conclusion

Claims 19-30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703)

Art Unit: 1631

305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran

mam
March 14, 2003

Michael P. Woodward
MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600